UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

April 17, 2009

**MEMORANDUM**

SUBJECT: Efficacy Review for PeridoxRTU™;
EPA Reg. No. 81073-G;
DP Barcode: D361064

FROM: Lorilyn M. Montford 5/21/09
Efficacy Evaluation Team
Antimicrobials Division (7510P)

THRU: Dr. Tajah Blackburn, Team Leader
Efficacy Evaluation Team
Antimicrobials Division (7510P) 5/21/09

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

TO: Marshall Swindell, PM 33/Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: Clean Earth Technologies, LLC
13378 Lakefront Drive
St. Louis, MO 63045

FORMULATION FROM LABEL:

| Active Ingredient(s) | % by wt. |
|---|---|
| Hydrogen Peroxide | 4.40% |
| Peroxyacetic Acid | 0.23% |
| Inert Ingredients | 95.40% |
| Total | 100.00% |

## I BACKGROUND

The product, Peridox RTU (EPA File Symbol 81073-G), is a new product. The applicant requested to register the ready-to-use product for use as a disinfectant (bactericide, fungicide, tuberculocide, sporicide, virucide), sanitizer, mildewcide, and deodorizer on hard, non-porous surfaces in household, institutional, industrial, commercial, animal care, and hospital or medical environments. The label claims that the product is effective as a disinfectant in the presence of a 5% organic soil load. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121; and MicroBioTest, Inc., located at 105 Carpenter Drive in Sterling, VA 20164.

This data package contained a letter from the applicant's representative to the Agency (dated January 6, 2009), EPA Form 8570-4 (Confidential Statement of Formula), twenty five studies (MRID 476375-07, 476375-09 through 476375-31, and 476448-01, Statements of No Data Confidentiality Claims for all twenty five studies, and the proposed label.

Note: EPA Form 8570-4 (Confidential Statement of Formula) contains Confidential Business Information. Data or information claimed by the applicant to be FIFRA confidential has not been included in this report.

## II USE DIRECTIONS

The product is designed for use on hard, non-porous surfaces, including: ambulance equipment, appliances, bath mats (plastic or rubber), bath tubs, bathroom fixtures, bed railings, bench tops and benches, cabinets, carts, chairs, counters and countertops, desks, display cases, doorknobs, drain troughs, drip pans, equipment, examination tables, faucets, feeders, floors, fountains, furniture, gurneys, hampers, hand railings, infant incubators and care cribs, kitchen fixtures, LCD screens, processing equipment, racks, shelves, shower stalls, showers, sinks, stall doors, stretchers, tables, tabletops, telephones, tiled walls, toilet seats, towel dispensers, troughs, vanities, and walls. The proposed label indicates that the product may be used on hard, non-porous surfaces including: aluminum, brass, copper, Corian, glass, glazed tile, laminated surfaces, nickel, painted surfaces, plastic (e.g., acrylic, LDPE, HDPE, polycarbonate, polypropylene, polyurethane, PVC, vinyl), porcelain, silicone rubber, and stainless steel. Directions on the proposed label provide the following information regarding use of the product:

> As a disinfectant: Wet or immerse surfaces completely with the product. An application rate of greater than 50 mL/$m^2$ is recommended. Surfaces must remain wet for 2 minutes (1 minute against *Aspergillus niger*, *Candida albicans*, and *Trichophyton mentagrophytes*). Air dry or remove solution and entrapped soil with a dry, clean cloth or wipe.
>
> As a sanitizer: Wet or immerse surfaces completely with the product prepared at half-strength. Surfaces must remain wet for 1 minute. Remove excess with a clean, dry cloth or allow surfaces to air dry. [Note: The label is incorrect; studies demonstrated efficacy of the product at full strength.]

## III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella enterica* (ATCC 10708; formerly *Salmonella choleraesuis*), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria)

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using the AOAC Germicidal Spray Products as Disinfectants Method)

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Germicidal Spray Products as Disinfectants Method contains procedures for testing fungicidal activity. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, the Agency is accepting studies with dried carrier counts that are at least $10^4$ for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. EPA recognizes laboratories are experiencing problems in maintaining dried carrier counts at the $10^6$ level. This interim policy will be in effect until the Agency determines that the laboratories are able to achieve consistent carrier counts at the $10^6$ level.

Sporicidal Disinfectant against *Clostridium difficile* (Using ASTM E 2197)

The Agency has established interim guidance for the efficacy evaluation of antimicrobial products (e.g., dilutable products, ready-to-use products, spray products, towelettes) that are labeled for use to treat hard, non-porous surfaces in healthcare settings contaminated with spores of *Clostridium difficile*. The effectiveness of such a product must be substantiated by data derived from one of the following four test methods: Most recent version (2006) of AOAC Method 966.04: AOAC Sporicidal Activity of Disinfectants Test, Method I for *Clostridium sporogenes*; AOAC Method 2008.05: Quantitative Three Step Method (Efficacy of Liquid

Sporicides Against Spores of *Bacillus subtilis* on a Hard Nonporous Surface); ASTM E 2414-05: Standard Test Method for Quantitative Sporicidal Three Step Method (TSM) to Determine Efficacy of Liquids, Liquid Sprays, and Vapor or Gases on Contaminated Carrier Surfaces; or ASTM E 2197-02: Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides. Modifications to each test method will be necessary to specifically accommodate spores of *Clostridium difficile*. Because *Clostridium difficile* is an obligate anaerobe, testing should ensure adequate incubation conditions for the recovery of viable spores. The following toxigenic strains of *Clostridium difficile* may be used for testing: ATCC 700792, ATCC 43598, or ATCC 43599. All products must carry a pre-cleaning step, thus no organic soil should be added to the spore inoculum. Results must show a minimum 6 log reduction of viable spores in 10 minutes or less. Control carrier counts must be greater than $10^6$ spores/carrier.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least $10^4$ from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Virucides – Novel Virus Protocol Standards

To ensure that a virus protocol has been adequately validated, data should be provided from at least 2 independent laboratories for each product tested (i.e., 2 product lots per laboratory).

Sanitizers (For Non-Food Contact Surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces)

Sanitizing rinses may be formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, or anionic detergent-acid formulations. The effectiveness of such sanitizing rinses for previously cleaned, food contact surfaces must be substantiated by data derived from the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method. Data from the test on 1 sample from each of 3 different product lots, one of which is at least 60 days old against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) are required. When the effectiveness of the product in hard water is made, all required data must be developed at the hard water tolerance claimed. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, counts on the number controls for the product should fall between 75 and 125 x $10^6$/mL for percent reductions to be considered valid. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. A potable water rinse is not required (to remove the use solution for the treated surface) for products cleared for use on food contact surfaces under the Federal Food, Drug, and Cosmetic Act. Label directions must recommend a potable water rinse (to remove the use solution from the treated surface) under any other circumstances.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

## IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

**1. MRID 476375-07 "Fungicidal Germicidal Spray Method, Test Organism: *Aspergillus niger* (ATCC 16404)," for Peridox RTU, by Anne Stemper. Study conducted at ATS Labs. Study completion date – November 5, 2008. Amended report date – November 18, 2008. Project Number A06857.**

This study was conducted against *Aspergillus niger* (ATCC 16404). Three lots (Lot Nos. CET-R052208 SI71, CET-R080408 SI81, and CET-R080408 SI82) of the product, PeridoxRTU, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use, as a pump spray. A culture of the challenge microorganism was prepared in accordance with the published AOAC methods, with the following exceptions: (1) the culture was incubated for 5-12 days at 25-30°C (which differs from the AOAC method specification of 10-15 days at 25-30°C (for *Trichophyton mentagrophytes*)); and (2) the culture was not standardized (which differs from the AOAC method specification of diluting the stock suspension using physiological NaCl solution so that it contains 5 x $10^6$ conidia/mL (for *Trichophyton mentagrophytes*)). Fetal bovine serum was added to the conidial suspension to yield a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 10.0 µL (i.e., 0.01 mL) of a 5-12 day old suspension of the test organism. The inoculum was uniformly spread over the surface of each carrier. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity (which differs from the AOAC method specification of 30-40 minutes at 37°C). For each lot of product, separate carriers were sprayed (using 8 pumps) with the product at a distance of 6-8 inches from the carrier surface

until thoroughly wet. The carriers were allowed to remain wet for 1 minute at 23.9°C. Following the exposure period, the remaining liquid was drained from each carrier. Individual carriers were transferred to 20 mL of Sabouraud Dextrose Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. Carriers were transferred from the primary subcultures into individual secondary subcultures containing 20 mL of Sabouraud Dextrose Broth with 0.07% Lecithin and 0.5% Tween 80 at least 30 minutes following the first transfer. Subcultures were not gently shaken (which is a deviation from the AOAC method). All subcultures were incubated for 10 days at 25-30°C (which differs from the AOAC method specification of 7 days at 25-30°C (for *Trichophyton mentagrophytes*)). Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Testing deviated from AOAC method specifications with regard to culture preparation, carrier drying, and subculture incubation. These deviations appear to be acceptable.

**2. MRID 476375-09 "Fungicidal Germicidal Spray Method, Test Organism: *Candida albicans* (ATCC 10231)," for PeridoxRTU, by Anne Stemper. Study conducted at ATS Labs. Study completion date – November 25, 2008. Project Number A06858.**

This study was conducted against *Candida albicans* (ATCC 10231). Three lots (Lot Nos. CET-R052208 SI71, CET-R080408 SI81, and CET-R080408 SI82) of the product, PeridoxRTU, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17$^{th}$ Edition, 2000. Testing was conducted on October 15, 2008 and November 14, 2008. The product was received ready-to-use, as a pump spray. A culture of the challenge microorganism was prepared in accordance with the published AOAC methods, with the following exceptions: (1) the culture was incubated for 2 days at 25-30°C (which differs from the AOAC method specification of 10-15 days at 25-30°C (for *Trichophyton mentagrophytes*)); and (2) the culture was transferred to Butterfield's Buffer to target a culture suspension of 1 x $10^8$ CFU/mL (which differs from the AOAC method specification of diluting the stock suspension using physiological NaCl solution so that it contains 5 x $10^6$ conidia/mL (for *Trichophyton mentagrophytes*)). Fetal bovine serum was added to the conidial suspension to yield a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 10.0 µL (i.e., 0.01 mL) of a 2 day old suspension of the test organism. The inoculum was uniformly spread over the surface of each carrier. The carriers were dried for 30 minutes at 25-30°C at 65% relative humidity (which differs from the AOAC method specification of 30-40 minutes at 37°C). For each lot of product, separate carriers were sprayed (using 8 pumps) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 1 minute at 22.7°C at 34.0% relative humidity on October 15, 2008. The carriers were allowed to remain wet for 1 minute at 22.9°C at 27.5% relative humidity on November 14, 2008. Following the exposure period, the remaining liquid was drained from each carrier. Individual carriers were transferred to 20 mL of Sabouraud Dextrose Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. Carriers were transferred from the primary subcultures into individual secondary subcultures containing 20 mL of Sabouraud Dextrose Broth with 0.07% Lecithin and 0.5% Tween 80 at least 30 minutes following the first transfer. Subcultures were not gently shaken (which is a deviation from the AOAC method). All subcultures were incubated for 3 days at 25-30°C (which differs from the AOAC method specification of 7 days at 25-30°C (for *Trichophyton mentagrophytes*)). The subcultures from testing conducted on October 15, 2008 were refrigerated for 2 days at 2-8°C prior to examination. Following incubation or incubation and storage, the subcultures were examined for

the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Testing conducted on October 15, 2008 demonstrated growth of *Candida albicans* in one secondary subculture of one of the product lots tested (i.e., Lot No. CET-R080408 SI82). Testing was repeated on November 14, 2008 to evaluate for the potential of false positives. No growth was observed in the repeat test.

Note: Testing deviated from AOAC method specifications with regard to culture preparation, carrier drying, and subculture incubation. These deviations appear to be acceptable.

**3. MRID 476375-10 "Virucidal Effectiveness Test, Human Immunodeficiency Virus Type 1" for PeridoxRTU, by S. Steve Zhou. Study conducted at MicroBioTest, Inc. Study completion date – October 31, 2008. Amended report date – December 4, 2008. Laboratory Project Identification Number 535-120.**

This study was conducted against Human immunodeficiency virus type 1 (HIV-1; obtained from ZeptoMetrix Corporation), using C8166 cells (obtained from the University of Pennsylvania) as the host system. Three lots (Lot Nos. CET-R 080408 SI79, CET-R 080408 SI80, and CET-R 052208 SI81) of the product, PeridoxRTU, were tested according to MicroBioTest Protocol "Virucidal Effectiveness Test, Human Immunodeficiency Virus Type 1," dated July 24, 2008 (copy provided). The product was received ready-to-use. The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum over the underside of separate sterile glass Petri dishes. The virus films were allowed to dry for 40 minutes at 23°C. Five replicates per product lot were tested. For each lot of product, separate dried virus films were sprayed with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 19-20°C. Following exposure, the plates were neutralized with 2.0 mL of RPMI 1640 with 0.5% Catalase and 0.5% Hepes. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in RPMI 1640 containing 5% fetal bovine serum. C8166 cells in multi-well culture dishes were inoculated in octuplicate with selected dilutions. The cultures were incubated for 9-12 days at 36±2°C in 5±1% $CO_2$. The plates were re-fed as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, column titer, cytotoxicity, and neutralizer effectiveness/ viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

Note: The initial laboratory was amended to revise the name of the product, add the percentages of the active ingredients, and add page numbers to the study appendix.

Note: The laboratory reported a failed trial set up on September 12, 2008. In the trial, no virus was detected in any of the controls. Thus, the study was invalid. Testing was repeated on October 13, 2008 with acceptable results.

Note: Protocol deviations/amendments reported in the study were reviewed.

**4. MRID 476375-11 "Virucidal Effectiveness Test, Avian Influenza virus (H5N1)**

**(NIBRG-14)" for PeridoxRTU, by S. Steve Zhou. Study conducted at MicroBioTest, Inc. Study completion date – October 31, 2008. Amended report date – December 4, 2008. Laboratory Project Identification Number 535-121.**

This study was conducted against Avian influenza virus (H5N1) (NIBRG-14) (obtained from Charles River Laboratory), using MDCK cells (ATCC CCL-34) as the host system. Two lots (Lot Nos. CET-R 080408 SI79 and CET-R 080408 SI80) of the product, PeridoxRTU, were tested according to MicroBioTest Protocol "Virucidal Effectiveness Test, Avian Influenza virus (H5N1) (NIBRG-14)," dated September 3, 2008 (copy provided). The product was received ready-to-use. The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum over the underside of separate sterile glass Petri dishes. The virus films were allowed to dry for 30 minutes at 21-22°C. For each lot of product, separate dried virus films were sprayed with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 20°C. Following exposure, the plates were neutralized with 2.0 mL of Minimum Essential Medium with 1% Polysorbate 80, 0.1% Catalase, and 0.1% sodium thiosulfate. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in Minimum Essential Medium with 1.0 µg/mL trypsin. MDCK cells in multi-well culture dishes were inoculated in quadruplicate with selected dilutions. The cultures were incubated for 4-6 days at 36±2°C in 5±1% $CO_2$. The plates were re-fed as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, column titer, cytotoxicity, and neutralizer effectiveness/ viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

Note: The initial laboratory was amended to revise the name of the product, add the percentages of the active ingredients, and add page numbers to the study appendix.

Note: Protocol deviations/amendments reported in the study were reviewed.

**5. MRID 476375-12 "Virucidal Effectiveness Test, Adenovirus Type 2" for PeridoxRTU, by S. Steve Zhou. Study conducted at MicroBioTest, Inc. Study completion date – October 31, 2008. Amended report date – December 4, 2008. Laboratory Project Identification Number 535-124.**

This study was conducted against Adenovirus type 2 (ATCC VR-846), using A549 cells (ATCC CCL-185) as the host system. Two lots (Lot Nos. CET-R 080408 SI79 and CET-R 080408 SI80) of the product, PeridoxRTU, were tested according to MicroBioTest Protocol "Virucidal Effectiveness Test, Adenovirus Type 2," dated September 3, 2008 (copy provided). The product was received ready-to-use. The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum over the underside of separate sterile glass Petri dishes. The virus films were allowed to dry for 30 minutes at 21-22°C. For each lot of product, separate dried virus films were sprayed with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 19°C. Following exposure, the plates were neutralized with 2.0 mL of fetal bovine serum with 1% Polysorbate 80, 0.1% Catalase, and 0.1% sodium thiosulfate. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in DMEM containing 5% fetal bovine serum. A549 cells in multi-well culture dishes were

inoculated in octuplicate with selected dilutions. The cultures were incubated for 11-14 days at 36±2°C in 5±1% $CO_2$. The plates were re-fed as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, column titer, cytotoxicity, and neutralizer effectiveness/ viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

Note: The initial laboratory was amended to revise the name of the product, add the percentages of the active ingredients, and add page numbers to the study appendix.

Note: Protocol deviations/amendments reported in the study were reviewed.

**6. MRID 476375-13 "Virucidal Effectiveness Test, Rhinovirus" for PeridoxRTU, by S. Steve Zhou. Study conducted at MicroBioTest, Inc. Study completion date – October 31, 2008. Amended report date – December 4, 2008. Laboratory Project Identification Number 535-125.**

This study was conducted against Rhinovirus type 42 (ATCC VR-338), using H1-HeLa cells (ATCC CRL-1958) as the host system. Two lots (Lot Nos. CET-R 080408 SI79 and CET-R 080408 SI80) of the product, PeridoxRTU, were tested according to MicroBioTest Protocol "Virucidal Effectiveness Test, Rhinovirus," dated September 3, 2008 (copy provided). The product was received ready-to-use. The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum over the underside of separate sterile glass Petri dishes. The virus films were allowed to dry for 30 minutes at 20°C. For each lot of product, separate dried virus films were sprayed with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 20°C. Following exposure, the plates were neutralized with 2.0 mL of fetal bovine serum with 1% Polysorbate 80, 0.1% Catalase, and 0.1% sodium thiosulfate. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in RPMI 1640 containing 5% fetal bovine serum. H1-HeLa cells in multi-well culture dishes were inoculated in octuplicate with selected dilutions. The cultures were incubated for 7-9 days at 33±2°C in 5±1% $CO_2$. The plates were re-fed as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, column titer, cytotoxicity, and neutralizer effectiveness/ viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed.

**7. MRID 476375-14 "Virucidal Effectiveness Test, Herpes Simplex Virus Type 1" for PeridoxRTU, by S. Steve Zhou. Study conducted at MicroBioTest, Inc. Study completion date – October 28, 2008. Amended report date – December 4, 2008. Laboratory Project Identification Number 535-122.**

This study was conducted against Herpes simplex virus type 1 (ATCC VR-260), using Vero cells (ATCC CCL-81) as the host system. Two lots (Lot Nos. CET-R 080408 SI79 and CET-R 080408 SI80) of the product, PeridoxRTU, were tested according to MicroBioTest Protocol "Virucidal Effectiveness Test, Herpes Simplex Virus Type 1," dated September 3, 2008 (copy provided). The product was received ready-to-use. The stock virus culture contained at

least a 5% organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum over the underside of separate sterile glass Petri dishes. The virus films were allowed to dry for 18 minutes at 23°C. For each lot of product, separate dried virus films were sprayed with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 19-20°C. Following exposure, the plates were neutralized with 2.0 mL of newborn calf serum with 1% Polysorbate 80, 0.1% Catalase, and 0.1% sodium thiosulfate. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in RPMI 1640 containing 5% newborn calf serum. Vero cells in multi-well culture dishes were inoculated in quadruplicate with selected dilutions. The cultures were incubated for 6-8 days at 36±2°C in 5±1% $CO_2$. The plates were re-fed as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, column titer, cytotoxicity, and neutralizer effectiveness/ viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed.

**8. MRID 476375-15 "Virucidal Effectiveness Test, Herpes Simplex Virus Type 2" for PeridoxRTU, by S. Steve Zhou. Study conducted at MicroBioTest, Inc. Study completion date – October 28, 2008. Amended report date – December 4, 2008. Laboratory Project Identification Number 535-123.**

This study was conducted against Herpes simplex virus type 2 (ATCC VR-734), using Vero cells (ATCC CCL-81) as the host system. Two lots (Lot Nos. CET-R 080408 SI79 and CET-R 080408 SI80) of the product, PeridoxRTU, were tested according to MicroBioTest Protocol "Virucidal Effectiveness Test, Herpes Simplex Virus Type 2," dated September 3, 2008 (copy provided). The product was received ready-to-use. The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum over the underside of separate sterile glass Petri dishes. The virus films were allowed to dry for 12 minutes at 23°C. For each lot of product, separate dried virus films were sprayed with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 19°C. Following exposure, the plates were neutralized with 2.0 mL of newborn calf serum with 1% Polysorbate 80, 0.1% Catalase, and 0.1% sodium thiosulfate. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephacryl columns, and diluted serially in RPMI 1640 containing 5% newborn calf serum. Vero cells in multi-well culture dishes were inoculated in quadruplicate with selected dilutions. The cultures were incubated for 6-8 days at 36±2°C in 5±1% $CO_2$. The plates were re-fed as necessary. Following incubation, the cultures were examined for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, plate recovery count, column titer, cytotoxicity, and neutralizer effectiveness/ viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed.

**9. MRID 476375-16 "Virucidal Efficacy of a Disinfectant for Use on Inanimate**

**Environmental Surfaces, Virus: Poliovirus type 1" for PeridoxRTU, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – December 16, 2008. Project Number A06944.**

This study was conducted against Poliovirus type 1 (Strain Chat (Sabin); ATCC VR-1562), using Vero cells (ATCC CCL-81, OH; propagated in-house) as the host system. Three lots (Lot Nos. CET-R052208 SI71, CET-R080408 SI81, and CET-R080408 SI82) of the product, PeridoxRTU, were tested according to ATS Labs Protocol No. CTL01100908.POL (copy provided). The product was received ready-to-use, as a pump spray. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the underside of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 55% relative humidity. Five replicates per product lot were tested. For each lot of product, separate dried virus films were sprayed with the product (25 pumps; approximately 15 seconds) at a distance of 4-6 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Vero cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$. The cultures were scored periodically for 10 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: The applicant reported a failed trial set up on November 4, 2008. In the trial, a dried virus count of at least $10^4$ was not achieved. Thus, this study was invalid. Testing was repeated on November 21, 2008. See Attachment I of the laboratory report.

**10. MRID 476375-17 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Avian Influenza A (H3N2) virus (Avian Reassortant)" for PeridoxRTU, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – December 2, 2008. Project Number A06994.**

This study was conducted against Avian influenza A virus (H3N2) (Avian Reassortant; Strain A/Washington/897/80 X A/Mallard/New York/6750/78; ATCC VR-2072), using Rhesus monkey kidney cells (obtained from ViroMed Laboratories, Inc., Cell Culture Division) as the host system. Two lots (Lot Nos. CET-R080408 SI81 and CET-R080408 SI82) of the product, PeridoxRTU, were tested according to ATS Labs Protocol No. CTL01100908.AFLU (copy provided). The product was received ready-to-use, as a pump spray. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the underside of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were sprayed with the product (25 pumps; approximately 15 seconds) at a distance of 4-6 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 1% heat-inactivated fetal

bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Rhesus monkey kidney cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

**11. MRID 476375-18 "Sanitizer Test for Non-Food Contact Surfaces," Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352), for PeridoxRTU, by Kathryn D. Dormstetter. Study conducted at MicroBioTest, Inc. Study completion date – November 25, 2008. Laboratory Project Identification Number 535-126.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three lots (Lot Nos. CET-R 080408 SI79, CET-R 080408 SI80, and CET-R 052208 SI71) of the product, PeridoxRTU, were tested according to MicroBioTest Protocol "Sanitizer Test for Non-Food Contact Surfaces," dated September 24, 2008 (copy provided). At least one of the product lots tested (i.e., Lot No. CET-R 052208 SI71) was at least 60 days old at the time of testing. The product was received ready-to-use. Heat-inactivated horse serum was added to each inoculum to achieve a 5% organic soil load. An unspecified number (presumably five) of sterile glass carriers per product lot per microorganism were inoculated with an unspecified amount of a 20-24 hour old suspension of the test organism. The inoculum presumably was spread over the surface of each carrier. Stainless steel carriers, glazed ceramic tiles, glazed porcelain tiles, and plastic PVC tiles were also tested in a similar manner. The carriers were dried for an unspecified amount of time presumably at room temperature. Each carrier was sprayed with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. Each carrier remained in contact with the product for 30 seconds at 19-21°C. After exposure, each carrier presumably was placed into a sterile jar containing DE Neutralizing Broth with Catalase. Presumably, the jars were rotated vigorously on an even plane to suspend the surviving organisms. Presumably, within 30 minutes of the addition of the neutralizer, 1.0 mL aliquots of the $10^0$ and $10^{-1}$ dilutions were plated in duplicate on a suitable agar. All plates were incubated for 48±2 hours at 37±2°C. Following incubation and storage, the subcultures were visually enumerated. Controls included parallel and zero time controls and those for sterility, neutralizer effectiveness, and confirmation of the challenge microorganisms.

Note: Protocol deviations/amendments reported in the study were reviewed.

**12. MRID 476375-19 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Human Coronavirus" for PeridoxRTU, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – November 25, 2008. Project Number A06992.**

This study was conducted against Human coronavirus (Strain 229E; ATCC VR-740), using WI-38 cells (ATCC CCL-75; propagated in-house) as the host system. Two lots (Lot Nos. CET-R080408 SI81 and CET-R080408 SI82) of the product, PeridoxRTU, were tested according to ATS Labs Protocol No. CTL01100908.COR (copy provided). The product was

received ready-to-use, as a pump spray. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the underside of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were sprayed with the product (25 pumps; approximately 20 seconds) at a distance of 4-6 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 2% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. WI-38 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% $CO_2$. The cultures were scored periodically for 9 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

**13. MRID 476375-20 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Influenza A virus" for PeridoxRTU, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – November 26, 2008. Project Number A06995.**

This study was conducted against Influenza A virus (Strain Hong Kong; ATCC VR-544), using Rhesus monkey kidney cells (obtained from ViroMed Laboratories, Inc., Cell Culture Division) as the host system. Two lots (Lot Nos. CET-R080408 SI81 and CET-R080408 SI82) of the product, PeridoxRTU, were tested according to ATS Labs Protocol No. CTL01100908.FLUA (copy provided). The product was received ready-to-use, as a pump spray. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the underside of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were sprayed with the product (25 pumps; approximately 15 seconds) at a distance of 4-6 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Rhesus monkey kidney cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

**14. MRID 476375-21 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Influenza B virus" for PeridoxRTU, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – December 3, 2008. Project Number A07020.**

This study was conducted against Influenza B virus (Strain B/Hong Kong/5/72; ATCC VR-823), using Rhesus monkey kidney cells (obtained from ViroMed Laboratories, Inc., Cell Culture Division) as the host system. Two lots (Lot Nos. CET-R080408 SI81 and CET-R080408 SI82) of the product, PeridoxRTU, were tested according to ATS Labs Protocol No. CTL01100908.FLUB (copy provided). The product was received ready-to-use, as a pump spray. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the underside of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were sprayed with the product (25 pumps; approximately 15 seconds) at a distance of 4-6 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Rhesus monkey kidney cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$. The cultures were scored periodically for 9 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

**15. MRID 476375-22 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Norovirus" for PeridoxRTU, by Karen M. Ramm. Study conducted at ATS Labs. Study completion date – December 9, 2008. Project Number A07022.**

This study, under the direction of Study Director Karen M. Ramm, was conducted against Feline calicivirus as a surrogate for Norovirus (Strain F-9; ATCC VR-782), using Crandel Reese feline kidney cells (CRFK cells; ATCC CCL-94; propagated in-house) as the host system. Three lots (Lot Nos. CET-R052208 SI71, CET-R080408 SI81, and CET-R080408 SI82) of the product, PeridoxRTU, were tested according to ATS Labs Protocol No. CTL01071108.FCAL.1 (copy provided). The product was received ready-to-use, as a pump spray. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the underside of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 50% relative humidity. Five replicates per product lot were tested. For each lot of product, separate dried virus films were sprayed with the product (25 pumps; approximately 15 seconds) at a distance of 4-6 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 23.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns. This dilution was considered the $10^{-1}$ dilution. A 0.2 mL aliquot of the virus was re-suspended in approximately 2.0 mL of test substance, which equals a 1:10 dilution. The filtrates were then diluted serially in Minimum Essential Medium supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% $CO_2$. The cultures were scored periodically for 7 days for the presence or absence of specified cytopathic effects (i.e., small, rounding of the cells, with a slight granular look), cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and

neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

**16. MRID 476375-23 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Norovirus – Confirmatory Assay" for PeridoxRTU, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – December 3, 2008. Project Number A07019.**

This confirmatory study, under the direction of Study Director Kelleen Gutzmann, was conducted against Feline calicivirus as a surrogate for Norovirus (Strain F-9; ATCC VR-782), using Crandel Reese feline kidney cells (CRFK cells; ATCC CCL-94; propagated in-house) as the host system. One lot (CET-R080408 SI81) of the product, PeridoxRTU, was tested according to ATS Labs Protocol No. CTL01071108.FCAL.2 (copy provided). The product was received ready-to-use, as a pump spray. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the underside of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.1°C at 51% relative humidity. Two replicates for the single product lot were tested. For the single product lot, separate dried virus films were sprayed with the product (25 pumps; approximately 15 seconds) at a distance of 4-6 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 20.1°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns. This dilution was considered the $10^{-1}$ dilution. A 0.2 mL aliquot of the virus was re-suspended in approximately 2.0 mL of test substance, which equals a 1:10 dilution. The filtrates were then diluted serially in Minimum Essential Medium supplemented with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% $CO_2$. The cultures were scored periodically for 7 days for the presence or absence of specified cytopathic effects (i.e., small, rounding of the cells, with a slight granular look), cytotoxicity, and viability. Controls included those for input virus titer, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

**17. MRID 476375-24 "AOAC Germicidal Spray Test – Healthcare," Test Organisms: *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), and *Pseudomonas aeruginosa* (ATCC 15442), for PeridoxRTU, by Adam A. Peters. Study conducted at MicroBioTest, Inc. Study completion date – October 1, 2008. Amended report date – December 4, 2008. Laboratory Project Identification Number 535-115.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), and *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. CET-R 080408 SI79, CET-R 080408 SI80, and CET-R 052208 SI71) of the product, PeridoxRTU, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. At least one of the product lots tested (i.e., Lot No. CET-R 052208 SI71) was at least 60 days old at the time of testing. The product was received ready-to-use. Cultures of the challenge microorganisms were prepared in accordance with the published AOAC methods, with the following exceptions: (1) the *Pseudomonas aeruginosa* culture was incubated for 48-54 hours (which differs from the AOAC method specification of 18-24 hours); and (2) the *Staphylococcus aureus* and *Salmonella*

*enterica* cultures were incubated for 48-54 hours (which differs from the AOAC method specification of 48 hours for all bacterial cultures except *Pseudomonas aeruginosa*). Heat-inactivated horse serum was added to the inoculum to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01-0.03 mL of a 48-54 hour old suspension of the test organism. Inoculum was transferred onto a one square inch area of each carrier and immediately spread uniformly over the entire area. The carriers were dried for 20-40 minutes at 37±2°C (which differs from the AOAC method specification of 30-40 minutes at 37°C). For each lot of product, separate carriers were sprayed with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 21°C. [It appears that remaining liquid on the carriers was not drained off, as specified in the AOAC method.] Following the exposure period, individual carriers were transferred to tubes containing DE Neutralizing Broth with 0.02 mL of 1.8% Catalase to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method. All subcultures were incubated for 48±2 hours at 37±2°C (which differs from the AOAC method specification of 48 hours at 37°C). Due to the opacity of the neutralizer, all *Pseudomonas aeruginosa* subcultures were streaked onto Tryptic Soy Agar and incubated for 24±2 hours at 37±2°C. Following incubation, the subcultures and streaks were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness, bacteriostasis, and confirmation of the challenge microorganisms.

Note: The initial laboratory report was amended to revise the name of the product, correct the product lot numbers, correct the percentages of the active ingredients, and add page numbers to the study appendix. In addition, the product application procedures were added to the "Test Conditions" section, and minor formatting changes were made.

Note: Testing deviated from AOAC method specifications with regard to culture preparation, carrier drying, and subculture incubation. These deviations appear to be acceptable.

**18. MRID 476375-25 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Reovirus" for PeridoxRTU, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – November 24, 2008. Project Number A06993.**

This study was conducted against Reovirus (Strain Abney; ATCC VR-232), using LLC-$MK_2$ cells (obtained from ViroMed Laboratories, Inc., Minnetonka, MN) as the host system. Two lots (Lot Nos. CET-R080408 SI81 and CET-R080408 SI82) of the product, PeridoxRTU, were tested according to ATS Labs Protocol No. CTL01101008.REO (copy provided). The product was received ready-to-use, as a pump spray. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the underside of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each lot of product, separate dried virus films were sprayed with the product (25 pumps; approximately 20 seconds) at a distance of 4-6 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. LLC-$MK_2$ cells in multi-well culture dishes

were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

**19. MRID 476375-26 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Respiratory syncytial virus" for PeridoxRTU, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – December 3, 2008. Project Number A06964.**

This study was conducted against Respiratory syncytial virus (Strain Long; ATCC VR-26), using Hep-2 cells (human larynx carcinoma cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division, Minnetonka, MN) as the host system. Two lots (Lot Nos. CET-R080408 SI81 and CET-R080408 SI82) of the product, PeridoxRTU, were tested according to ATS Labs Protocol No. CTL01100908.RSV (copy provided). The product was received ready-to-use, as a pump spray. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the underside of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 52% relative humidity. For each lot of product, separate dried virus films were sprayed with the product (25 pumps; approximately 20 seconds) at a distance of 4-6 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Eagle's Minimum Essential Medium supplemented with 2% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL Fungizone, 10 µg/mL vancomycin, 2.0 mM L-glutamine, and 10 mM HEPES. Hep-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$. The cultures were scored periodically for 11 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

**20. MRID 476375-27 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Rotavirus" for PeridoxRTU, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – November 25, 2008. Project Number A07021.**

This study was conducted against Rotavirus (Strain WA; obtained from the University of Ottawa, Ontario, Canada), using MA-104 cells (Rhesus monkey kidney cells; obtained from Diagnostic Hybrids Inc., Athens, OH; propagated in-house) as the host system. Three lots (Lot Nos. CET-R052208 SI71, CET-R080408 SI81, and CET-R080408 SI82) of the product, PeridoxRTU, were tested according to ATS Labs Protocol No. CTL01100908.ROT (copy provided). The product was received ready-to-use, as a pump spray. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the underside of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 19.8°C at 50% relative humidity. Five replicates per product lot were tested. For each lot of product, separate dried virus films were sprayed with the product (25 pumps; approximately 20 seconds) at a distance of 4-6

inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in serum-free Minimum Essential Medium supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 0.5 µg/mL trypsin, and 2.0 mM L-glutamine. MA-104 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The inoculum was allowed to adsorb for 60-68 minutes at 36-38°C in a humidified atmosphere of 5-7% $CO_2$. Following adsorption, the cultures were re-fed and incubated at 36-38°C in a humidified atmosphere of 5-7% $CO_2$. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: ATS Laboratory Protocol No. CTL01100908.ROT, included as part of the laboratory study, is marked as "Proprietary Information."

**21. MRID 476375-28 "Standard Quantitative Disk Carrier Test Method, Test Organism: *Clostridium difficile* (spore form) (ATCC 700792)" for PeridoxRTU, by David Rottjakob. Study conducted at ATS Labs. Study completion date – December 30, 2008. Project Number A07171.**

This study was conducted against *Clostridium difficile* (spore form) (ATCC 700792). Three lots (Lot Nos. CET-R080408 SI81, CET-R080408 SI82, and CET-R052208 SI71) of the product, PeridoxRTU, were tested using the ASTM E 2197-02, Standard Quantitative Disk Carrier Test Method for Determining the Bactericidal, Virucidal, Fungicidal, Mycobactericidal and Sporicidal Activities of Liquid Chemical Germicides. The product was received ready-to-use. Cultures of the challenge microorganism were prepared in accordance with the laboratory protocol. A soil load mixture consisting of tryptone, bovine serum albumin, and bovine mucin was added to the inoculum to achieve a standard organic soil load. Ten (10) sterile brushed stainless steel disk carriers per product lot were inoculated with 25 µL (i.e., 0.025 mL) of a 7 day old suspension of the test organism. The inoculum was not spread. The carriers were dried for approximately 5 days under ambient conditions under a vacuum in a desiccator containing active desiccant. Each carrier was placed into a separate sterile QCT vial with the inoculated side of the carrier facing up. For each lot of product, separate carriers were exposed to 50 µL (i.e., 0.05 mL) of the product for 7 minutes at 20°C. Following exposure, 10.0 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase was added to each QCT vial. The vials were vortex mixed for approximately 45-60 seconds. Each carrier was examined to verify that the inoculum was completely eluted from the carrier surface. When visible inoculum remained, the carrier surface was scraped with a sterile pipette while flushing with eluate. The neutralized organism-product mixtures ($10^0$ dilutions) were filtered in individual sterile pre-wetted filter units with 0.45 µm porosity. Sterile saline (10.0 mL) was added to each vial and vortex mixed. The rinse solution then was filtered using the same filter membrane. This rinse step was repeated a total of three times. Each filter membrane was removed aseptically from the filter unit and placed onto the surface of a plate containing *Clostridium difficile* Selective Agar. The plates were incubated for 45 hours at 35-37°C under anaerobic conditions and then stored for 3 days at 2-8°C. Following incubation and storage, the plates were enumerated. Controls included those for initial suspension population count, carrier population count, purity, sterility, neutralization confirmation, and acid resistance.

**22. MRID 476375-29 "AOAC Germicidal Spray Test – Supplemental" for PeridoxRTU, by Kathryn D. Dormstetter. Study conducted at MicroBioTest, Inc. Study completion date – October 30, 2008. Amended report date – December 4, 2008. Laboratory Project Identification Number 535-118.**

This study was conducted against *Acinetobacter baumannii* (ATCC 19606), *Candida albicans* (ATCC 10231), *Campylobacter jejuni* (ATCC 29428), *Escherichia coli* O157:H7 (ATCC 35150), Extended spectrum β-lactamase *Escherichia coli* (ATCC BAA-196), Vancomycin-resistant *Enterococcus faecalis* (ATCC 51299), *Enterococcus hirae* (ATCC 10541), *Haemophilus influenzae* (ATCC 19418), *Klebsiella pneumoniae* (ATCC 4352), *Legionella pneumophila* (ATCC 33153), *Proteus vulgaris* (ATCC 27973), *Serratia marcescens* (ATCC 13880), *Shigella sonnei* (ATCC 11060), Methicillin-resistant *Staphylococcus aureus* (ATCC 33592), Community-acquired Methicillin-resistant *Staphylococcus aureus* (Genotype 300, Clinical Isolate 08001; obtained from the University of Louisville Hospital), Penicillin-resistant *Streptococcus pneumoniae* (ATCC 700671), and *Streptococcus pyogenes* (ATCC 19615). Three lots (Lot Nos. CET-R 080408 SI79, CET-R 080408 SI80, and CET-R 052208 SI71) of the product, PeridoxRTU, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16$^{th}$ Edition, 1995. The product was received ready-to-use. Cultures of the challenge microorganisms were prepared in accordance with the published AOAC methods, with the following exception: the cultures were incubated for 48-54 hours (which differs from the AOAC method specification of 48 hours for all bacterial cultures except *Pseudomonas aeruginosa*). Heat-inactivated horse serum was added to the inoculum to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01-0.03 mL of a 48-54 hour old suspension of the test organism. Inoculum was transferred onto a one square inch area of each carrier and immediately spread uniformly over the entire area. The carriers were dried for 20-40 minutes at 37±2°C (which differs from the AOAC method specification of 30-40 minutes at 37°C). For each lot of product, separate carriers were sprayed with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 20°C. Following exposure, the remaining liquid was drained each carrier. Individual carriers were transferred to tubes containing DE Neutralizing Broth with 0.02 mL of 1.8% Catalase to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method. All subcultures were incubated for 48±2 hours at 37±2°C (which differs from the AOAC method specification of 48 hours at 37°C). All subcultures for *Haemophilus influenzae*, *Legionella pneumophila*, Penicillin-resistant *Streptococcus pneumoniae*, and *Streptococcus pyogenes* were incubated under 5% $CO_2$ (candle jar conditions). Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness, bacteriostasis, confirmation of the challenge microorganisms, and antibiotic resistance.

Note: The initial laboratory report was amended to revise the name of the product and correct the percentages of the active ingredients. In addition, minor formatting changes were made.

Note: The applicant reported testing conducted on September 8, 2008 and September 9, 2008. For these tests, testing was invalidated because the contact temperature was 24-25°C, which was not within the range of 20±1°C (ambient room temperature).

Note: Antibiotic resistance was verified for the following microorganisms: Methicillin-resistant *Staphylococcus aureus* (ATCC 33592; resistant to oxacillin), Vancomycin-resistant

*Enterococcus faecalis* (ATCC 51299; resistant to vancomycin), Penicillin-resistant *Streptococcus pneumoniae* (ATCC 700671; resistant to penicillin), Extended spectrum β-lactamase *Escherichia coli* (ATCC BAA-196; resistant to ceftazidime and penicillin), and Community-acquired Methicillin-resistant *Staphylococcus aureus* (Genotype 300, Clinical Isolate 08001; resistant to oxacillin). For each microorganism, an individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was added to the center of the plate. The plate was incubated for 24±2 hours at 37±2°C. Following incubation, the zone of inhibition was measured and documented. See pages 10 and 25 of the laboratory report.

**23. MRID 476375-30 "AOAC Germicidal Spray Test – Confirmatory" for PeridoxRTU, by Adam A. Peters. Study conducted at MicroBioTest, Inc. Study completion date – October 1, 2008. Amended report date – December 4, 2008. Laboratory Project Identification Number 535-116.**

This study was conducted against *Enterobacter aerogenes* (ATCC 13048), *Listeria monocytogenes* (ATCC 19111), *Salmonella typhimurium* (ATCC 13311), and *Vibrio cholerae* (ATCC 14035). Three lots (Lot Nos. CET-R 080408 SI79, CET-R 080408 SI80, and CET-R 052208 SI71) of the product, PeridoxRTU, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. The product was received ready-to-use. Cultures of the challenge microorganisms were prepared in accordance with the published AOAC methods, with the following exception: the cultures were incubated for 48-54 hours (which differs from the AOAC method specification of 48 hours for all bacterial cultures except *Pseudomonas aeruginosa*). Heat-inactivated horse serum was added to the inoculum to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01-0.03 mL of a 48-54 hour old suspension of the test organism. Inoculum was transferred onto a one square inch area of each carrier and immediately spread uniformly over the entire area. The carriers were dried for 20-40 minutes at 37±2°C (which differs from the AOAC method specification of 30-40 minutes at 37°C). For each lot of product, separate carriers were sprayed with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 21°C. [It appears that remaining liquid on the carriers was not drained off, as specified in the AOAC method.] Following the exposure period, individual carriers were transferred to tubes containing DE Neutralizing Broth with 0.02 mL of 1.8% Catalase to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method. All subcultures were incubated for 48±2 hours at 37±2°C (which differs from the AOAC method specification of 48 hours at 37°C). Following incubation, the subcultures and streaks were examined for the presence or absence of visible growth. Controls included those for carrier counts, sterility, viability, neutralizer effectiveness, bacteriostasis, and confirmation of the challenge microorganisms.

Note: The initial laboratory report was amended to revise the name of the product, correct the product lot numbers, and correct the percentages of the active ingredients. In addition, the product application procedures were added to the "Test Conditions" section, and minor formatting changes were made.

**24. MRID 476375-31 "Germicidal and Detergent Sanitizing Action of Disinfectants," Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11229), for PeridoxRTU, by Becky Lien. Study conducted at ATS Labs. Study completion date – December 19, 2008. Project Number A07104.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11229). Three lots (Lot Nos. CET-R080408 SI79, CET-R080408 SI82, and CET-R052208 SI71) of the product, PeridoxRTU, were tested using the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. At least one of the product lots tested (i.e., Lot No. CET-R052208 SI71) was at least 60 days old at the time of testing. The product was received ready-to-use. A culture of each challenge microorganism was prepared in accordance with the published AOAC method, with the following exception: the cultures were incubated for 23 hours at 35-37°C. The *Escherichia coli* culture was standardized with phosphate buffer dilution water using a spectrometer to target ~1.0 x $10^{10}$ organisms/mL. The *Staphylococcus aureus* culture did not need adjusting. [The AOAC method states to standardize the culture to give an average of 10 x $10^{9}$ organisms/mL.] The product was not tested in the presence of a 5% organic soil load. A 99-mL aliquot of each product lot for each test organism was transferred to a 250-300 mL Erlenmeyer flask and placed in a water bath at 20.0°C. One-mL bacterial suspension was added to each flask. One-mL aliquots of the bacterium-product mixture were transferred to 9 mL of Letheen Broth containing 1.0% sodium thiosulfate and 0.05% Catalase exactly 30 seconds after the addition of the bacterial suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots were plated in Tryptone Glucose Extract Agar. All plates were incubated for 46.5 hours at 35-37°C (which differs from the AOAC method specification of 48 hours at 35°C). The plates were stored for 3 days at 2-8°C prior to reading. Following incubation and storage, the colonies were counted. Controls included those for numbers count, purity, sterility, viability, and neutralization confirmation.

**25. MRID 476448-01 "Fungicidal Germicidal Spray Method, Test Organism: *Trichophyton mentagrophytes* (ATCC 9533)," for PeridoxRTU, by Anne Stemper. Study conducted at ATS Labs. Study completion date – November 5, 2008. Amended report date – November 18, 2008. Project Number A06859.**

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Three lots (Lot Nos. CET-R052208 SI71, CET-R080408 SI81, and CET-R080408 SI82) of the product, PeridoxRTU, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use, as a pump spray. A culture of the challenge microorganism was prepared in accordance with the published AOAC methods. Fetal bovine serum was added to the conidial suspension to yield a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 10.0 µL (i.e., 0.01 mL) of a 10-15 day old suspension of the test organism. The inoculum was uniformly spread over the surface of each carrier. The carriers were dried for 30 minutes at 35-37°C at 39% relative humidity (which is consistent with the AOAC method specification of 30-40 minutes at 37°C). For each lot of product, separate carriers were sprayed with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 1 minute at 23.1°C. Following the exposure period, the remaining liquid was drained from each carrier. Individual carriers were transferred to 20 mL of Sabouraud Dextrose Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. Carriers were transferred from the primary subcultures into individual secondary subcultures containing 20 mL of Sabouraud Dextrose Broth with 0.07% Lecithin and 0.5% Tween 80 at least 30 minutes following the first transfer. Subcultures were not gently shaken (which is a deviation from the AOAC method). All subcultures were incubated for 10 days at 25-30°C (which differs from the AOAC method specification of 7 days at 25-30°C (for *Trichophyton mentagrophytes*)). Following incubation, the subcultures were examined for the presence or absence of visible

growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

## V RESULTS

| MRID Number | Organism | No. Exhibiting Growth/ Total No. Tested | | | Carrier Counts (CFU/ Carrier) |
|---|---|---|---|---|---|
| | | Lot No. SI79[1] | Lot No. SI80[1] | Lot No. SI71[1] | |
| 476375-24 | *Staphylococcus aureus* | 0/60 | 0/60 | 0/60 | $2.0 \times 10^6$ |
| 476375-24 | *Salmonella enterica* | 0/60 | 0/60 | 0/60 | $6.4 \times 10^4$ |
| 476375-24 | *Pseudomonas aeruginosa* | 0/60 | 0/60 | 0/60 | $5.5 \times 10^5$ |
| 476375-29 | *Acinetobacter baumannii* | 0/10 | 0/10 | 0/10 | $1.7 \times 10^6$ |
| 476375-29 | *Candida albicans* | 0/10 | 0/10 | 0/10 | $4.3 \times 10^5$ |
| 476375-29 | *Campylobacter jejuni* | 0/10 | 0/10 | 0/10 | $3.1 \times 10^6$ |
| 476375-29 | *Escherichia coli* O157:H7 | 0/10 | 0/10 | 0/10 | $2.9 \times 10^5$ |
| 476375-29 | Extended spectrum β-lactamase *Escherichia coli* | 0/10 | 0/10 | 0/10 | $1.2 \times 10^6$ |
| 476375-29 | Vancomycin-resistant *Enterococcus faecalis* | 0/10 | 0/10 | 0/10 | $3.4 \times 10^6$ |
| 476375-29 | *Enterococcus hirae* | 0/10 | 0/10 | 0/10 | $6.2 \times 10^5$ |
| 476375-29 | *Haemophilus influenzae* | 0/10 | 0/10 | 0/10 | $4.9 \times 10^6$ |
| 476375-29 | *Klebsiella pneumoniae* | 0/10 | 0/10 | 0/10 | $3.1 \times 10^5$ |
| 476375-29 | *Legionella pneumophila* | 0/10 | 0/10 | 0/10 | $4.5 \times 10^5$ |
| 476375-29 | *Proteus vulgaris* | 0/10 | 0/10 | 0/10 | $1.4 \times 10^5$ |
| 476375-29 | *Serratia marcescens* | 0/10 | 0/10 | 0/10 | $7.2 \times 10^4$ |
| 476375-29 | *Shigella sonnei* | 0/10 | 0/10 | 0/10 | $2.1 \times 10^5$ |
| 476375-29 | Methicillin-resistant *Staphylococcus aureus* | 0/10 | 0/10 | 0/10 | $2.0 \times 10^6$ |
| 476375-29 | Community-acquired Methicillin-resistant | 0/10 | 0/10 | 0/10 | $2.4 \times 10^6$ |

| MRID Number | Organism | No. Exhibiting Growth/ Total No. Tested | | | Carrier Counts (CFU/ Carrier) |
|---|---|---|---|---|---|
| | | Lot No. SI79[1] | Lot No. SI80[1] | Lot No. SI71[1] | |
| | *Staphylococcus aureus* (Genotype 300, Clinical Isolate 08001) | | | | |
| 476375-29 | Penicillin-resistant *Streptococcus pneumoniae* | 0/10 | 0/10 | 0/10 | $2.4 \times 10^6$ |
| 476375-29 | *Streptococcus pyogenes* | 0/10 | 0/10 | 0/10 | $7.2 \times 10^5$ |
| 476375-30 | *Enterobacter aerogenes* | 0/10 | 0/10 | 0/10 | $8.3 \times 10^4$ |
| 476375-30 | *Listeria monocytogenes* | 0/10 | 0/10 | 0/10 | $5.0 \times 10^4$ |
| 476375-30 | *Salmonella typhimurium* | 0/10 | 0/10 | 0/10 | $6.8 \times 10^4$ |
| 476375-30 | *Vibrio cholerae* | 0/10 | 0/10 | 0/10 | $2.4 \times 10^6$ |

[1]Lot No. SI79 refers to Lot No. CET-R 080408 SI79; Lot No. SI80 refers to Lot No. CET-R 080408 SI80; and Lot No. SI71 refers to CET-R 052208 SI71.

| MRID Number | Organism | No. Exhibiting Growth/ Total No. Tested | | | Carrier Counts (CFU/ Carrier) |
|---|---|---|---|---|---|
| | | Lot No. SI71[1] | Lot No. SI81[1] | Lot No. SI82[1] | |
| 476375-07 | *Aspergillus niger* | 1°=0/10<br>2°=0/10 | 1°=0/10<br>2°=0/10 | 1°=0/10<br>2°=0/10 | $5.8 \times 10^5$ |
| 476375-09 | *Candida albicans*<br>Test Date: 10/15/2008 | 1°=0/10<br>2°=0/10 | 1°=0/10<br>2°=0/10 | 1°=0/10<br>2°=1/10 | $2.44 \times 10^5$ |
| | *Candida albicans*<br>Test Date: 11/14/2008 | --- | --- | 1°=0/10<br>2°=0/10 | $8.7 \times 10^4$ |
| 476448-01 | *Trichophyton mentagrophytes* | 1°=0/10<br>2°=0/10 | 1°=0/10<br>2°=0/10 | 1°=0/10<br>2°=0/10 | $2.0 \times 10^6$ |

[1]Lot No. SI71 refers to Lot No. CET-R052208 SI71; Lot No. SI81 refers to Lot No. CET-R080408 SI81; and Lot No. SI82 refers to CET-R080408 SI82.

| MRID Number | Organism | Lot No. | Average No. Surviving (CFU/carrier) | Carrier Population | Percent Reduction |
|---|---|---|---|---|---|
| 476375-28 | *Clostridium difficile* (spore form) | SI81[1] | <1 | $2.11 \times 10^6$ | >99.9999 |
| | | SI82[1] | <1 | $2.11 \times 10^6$ | >99.9999 |
| | | SI71[1] | <1 | $2.11 \times 10^6$ | >99.9999 |

[1]Lot No. SI81 refers to Lot No. CET-R080408 SI81; Lot No. SI82 refers to Lot No. CET-R080408 SI82; and Lot No. SI71 refers to CET-R052208 SI71.

| MRID Number | Organism | Results | | | | Plate Recovery Control ($TCID_{50}$/ mL) |
|---|---|---|---|---|---|---|
| | | | Lot No. SI79[1] | Lot No. SI80[1] | Lot No. SI71[1] | |
| 476375-10 | Human immunodeficiency virus type 1 | $10^{-2}$ dilutions | Cytotoxicity | | | $10^{6.80}$ |
| | | $10^{-3}$ to $10^{-7}$ dilutions | Complete inactivation | | | |
| | | $TCID_{50}$/ mL | $\leq 10^{3.83}$ | $\leq 10^{3.83}$ | $\leq 10^{3.83}$ | |
| | | Log reduction | $\geq 2.97$ $\log_{10}$ | | | |
| 476375-11 | Avian influenza virus (H5N1) | $10^{-2}$ to $10^{-3}$ dilutions | Cytotoxicity | | --- | $10^{7.50}$ |
| | | $10^{-4}$ to $10^{-6}$ dilutions | Complete inactivation | | --- | |
| | | $TCID_{50}$/ mL | $\leq 10^{3.83}$ | $\leq 10^{3.83}$ | --- | |
| | | Log reduction | $\geq 3.67$ $\log_{10}$ | | --- | |
| 476375-12 | Adenovirus type 2 | $10^{-2}$ to $10^{-3}$ dilutions | Cytotoxicity | | --- | $10^{8.68}$ |
| | | $10^{-4}$ to $10^{-6}$ dilutions | Complete inactivation | | --- | |
| | | $TCID_{50}$/ mL | $\leq 10^{4.83}$ | $\leq 10^{4.83}$ | --- | |
| | | Log reduction | $\geq 3.85$ $\log_{10}$ | | --- | |
| 476375-13 | Rhinovirus | $10^{-2}$ to $10^{-3}$ dilutions | Cytotoxicity | | --- | $10^{7.80}$ |
| | | $10^{-4}$ to $10^{-6}$ dilutions | Complete inactivation | | --- | |
| | | $TCID_{50}$/ mL | $\leq 10^{4.83}$ | $\leq 10^{4.83}$ | --- | |
| | | Log reduction | $\geq 2.97$ $\log_{10}$ | | --- | |
| 476375-14 | Herpes simplex virus type 1 | $10^{-2}$ to $10^{-3}$ dilutions | Cytotoxicity | | --- | $10^{\geq 7.50}$ |
| | | $10^{-4}$ to $10^{-7}$ dilutions | Complete inactivation | | --- | |
| | | $TCID_{50}$/ mL | $\leq 10^{3.83}$ | $\leq 10^{3.83}$ | --- | |
| | | Log reduction | $\geq 3.67$ $\log_{10}$ | | --- | |
| 476375-15 | Herpes simplex virus type 2 | $10^{-2}$ to $10^{-3}$ dilutions | Cytotoxicity | | --- | $10^{7.25}$ |
| | | $10^{-4}$ to $10^{-7}$ dilutions | Complete inactivation | | --- | |
| | | $TCID_{50}$/ mL | $\leq 10^{3.83}$ | $\leq 10^{3.83}$ | --- | |

| MRID Number | Organism | Results | | | | Plate Recovery Control ($TCID_{50}$/ mL) |
|---|---|---|---|---|---|---|
| | | | Lot No. SI79[1] | Lot No. SI80[1] | Lot No. SI71[1] | |
| | | Log reduction | $\geq$3.42 $log_{10}$ | | --- | |

[1]Lot No. SI79 refers to Lot No. CET-R 080408 SI79; Lot No. SI80 refers to Lot No. CET-R 080408 SI80; and Lot No. SI71 refers to CET-R 052208 SI71.

| MRID Number | Organism | Results | | | | Dried Virus Control ($TCID_{50}$/ 0.1 mL) |
|---|---|---|---|---|---|---|
| | | | Lot No. SI71[1] | Lot No. SI81[1] | Lot No. SI82[1] | |
| 476375-16 | Poliovirus type 1 | $10^{-1}$ to $10^{-7}$ dilutions | Complete inactivation[2] | | | $10^{4.9}$ |
| | | $TCID_{50}$/0.1 mL | $\leq 10^{0.5}$ (see note 2) | $\leq 10^{0.5}$ | $\leq 10^{0.5}$ | |
| 476375-17 | Avian influenza A virus (H3N2) | $10^{-1}$ to $10^{-7}$ dilutions | --- | Complete inactivation | | $10^{4.5}$ |
| | | $TCID_{50}$/0.1 mL | --- | $\leq 10^{0.5}$ | $\leq 10^{0.5}$ | |
| 476375-19 | Human coronavirus | $10^{-1}$ to $10^{-6}$ dilutions | --- | Complete inactivation | | $10^{4.5}$ |
| | | $TCID_{50}$/0.1 mL | --- | $\leq 10^{0.5}$ | $\leq 10^{0.5}$ | |
| 476375-20 | Influenza A virus | $10^{-1}$ to $10^{-7}$ dilutions | --- | Complete inactivation | | $10^{5.5}$ |
| | | $TCID_{50}$/0.1 mL | --- | $\leq 10^{0.5}$ | $\leq 10^{0.5}$ | |
| 476375-21 | Influenza B virus | $10^{-1}$ to $10^{-7}$ dilutions | --- | Complete inactivation | | $10^{4.5}$ |
| | | $TCID_{50}$/0.1 mL | --- | $\leq 10^{0.5}$ | $\leq 10^{0.5}$ | |
| 476375-25 | Reovirus | $10^{-1}$ to $10^{-7}$ dilutions | --- | Complete inactivation | | $10^{4.75}$ |
| | | $TCID_{50}$/0.1 mL | --- | $\leq 10^{0.5}$ | $\leq 10^{0.5}$ | |
| 476375-26 | Respiratory syncytial virus | $10^{-1}$ to $10^{-6}$ dilutions | --- | Complete inactivation | | $10^{4.75}$ |
| | | $TCID_{50}$/0.1 mL | --- | $\leq 10^{0.5}$ | $\leq 10^{0.5}$ | |
| 476375-27 | Rotavirus | $10^{-1}$ to $10^{-7}$ dilutions | Complete inactivation | | | $10^{6.1}$ |
| | | $TCID_{50}$/0.1 mL | $\leq 10^{0.5}$ | $\leq 10^{0.5}$ | $\leq 10^{0.5}$ | |

[1]Lot No. SI71 refers to Lot No. CET-R052208 SI71; Lot No. SI81 refers to Lot No. CET-R080408 SI81; and Lot No. SI82 refers to CET-R080408 SI82.

[2]In the study against Poliovirus type 1, cytotoxicity was observed in the $10^{-1}$ dilution of one of five

replicates for one of three product lots. The $TCID_{50}$/0.1 mL reported for this one replicate was $\leq 10^{1.5}$, corresponding to a log reduction of $\geq 3.4$ $log_{10}$. No cytotoxicity was observed in the other $10^{-1}$ dilutions.

| MRID Number | Organism | Results | | | | Dried Virus Control ($TCID_{50}$/ 0.1 mL) |
|---|---|---|---|---|---|---|
| | | | Lot No. SI71[1] | Lot No. SI81[1] | Lot No. SI82[1] | |
| 476375-22 | Feline calicivirus | $10^{-1}$ dilutions | Cytotoxicity[2] | --- | --- | $10^{5.5}$ to $10^{6.25}$ (average of $10^{6.05}$) |
| | | $10^{-2}$ to $10^{-4}$ dilutions | Complete inactivation | --- | --- | |
| | | $10^{-1}$ to $10^{-4}$ dilutions | --- | Complete inactivation | | |
| | | $TCID_{50}$/0.1 mL | $\leq 10^{1.3}$ (average) | $\leq 10^{0.5}$ | $\leq 10^{0.5}$ | |
| | | Log reduction | $\geq 4.75$ $log_{10}$ | --- | --- | |
| 476375-23 | Feline calicivirus | $10^{-1}$ to $10^{-4}$ dilutions | --- | Complete inactivation | --- | $10^{6.0}$ and $10^{6.5}$ |
| | | $TCID_{50}$/0.1 mL | --- | $\leq 10^{0.5}$ | --- | |

[1]Lot No. SI71 refers to Lot No. CET-R052208 SI71; Lot No. SI81 refers to Lot No. CET-R080408 SI81; and Lot No. SI82 refers to CET-R080408 SI82.
[2]In the initial study against Feline calicivirus, cytotoxicity was observed in the $10^{-1}$ dilution of four of five replicates for one of three product lots.

| MRID Number | Organism | Lot No. | Average No. Surviving | Microbes Initially Present | Percent Reduction |
|---|---|---|---|---|---|
| | | | (CFU/carrier) | | |
| **Glass Slide Carriers** | | | | | |
| 476375-18 | *Staphylococcus aureus* | SI79[1] | $<1.0 \times 10^1$ | $2.8 \times 10^5$ | >99.9 |
| | | SI80[1] | $<1.0 \times 10^1$ | $2.8 \times 10^5$ | >99.9 |
| | | SI71[1] | $<1.0 \times 10^1$ | $2.8 \times 10^5$ | >99.9 |
| | *Klebsiella pneumoniae* | SI79 | $<1.0 \times 10^1$ | $2.2 \times 10^5$ | >99.9 |
| | | SI80 | $<1.0 \times 10^1$ | $2.2 \times 10^5$ | >99.9 |
| | | SI71 | $<1.0 \times 10^1$ | $2.2 \times 10^5$ | >99.9 |
| **Stainless Steel Carriers** | | | | | |
| 476375-18 | *Staphylococcus aureus* | SI79 | $<1.0 \times 10^1$ | $1.1 \times 10^5$ | >99.9 |
| | | SI80 | $<1.0 \times 10^1$ | $1.1 \times 10^5$ | >99.9 |
| | | SI71 | $<1.0 \times 10^1$ | $1.1 \times 10^5$ | >99.9 |
| | *Klebsiella pneumoniae* | SI79 | $<1.0 \times 10^1$ | $1.3 \times 10^5$ | >99.9 |
| | | SI80 | $<1.0 \times 10^1$ | $1.3 \times 10^5$ | >99.9 |
| | | SI71 | $<1.0 \times 10^1$ | $1.3 \times 10^5$ | >99.9 |
| **Glazed Ceramic Tiles** | | | | | |
| 476375-18 | *Staphylococcus aureus* | SI79 | $<1.0 \times 10^1$ | $2.4 \times 10^5$ | >99.9 |
| | | SI80 | $<1.0 \times 10^1$ | $2.4 \times 10^5$ | >99.9 |
| | | SI71 | $<1.0 \times 10^1$ | $2.4 \times 10^5$ | >99.9 |

| MRID Number | Organism | Lot No. | Average No. Surviving | Microbes Initially Present | Percent Reduction |
|---|---|---|---|---|---|
| | | | (CFU/carrier) | | |
| | *Klebsiella pneumoniae* | SI79 | $<1.0 \times 10^1$ | $2.1 \times 10^5$ | >99.9 |
| | | SI80 | $<1.0 \times 10^1$ | $2.1 \times 10^5$ | >99.9 |
| | | SI71 | $<1.0 \times 10^1$ | $2.1 \times 10^5$ | >99.9 |
| **Glazed Porcelain Tiles** | | | | | |
| 476375-18 | *Staphylococcus aureus* | SI79 | $<1.0 \times 10^1$ | $4.3 \times 10^5$ | >99.9 |
| | | SI80 | $<1.0 \times 10^1$ | $4.3 \times 10^5$ | >99.9 |
| | | SI71 | $<1.0 \times 10^1$ | $4.3 \times 10^5$ | >99.9 |
| | *Klebsiella pneumoniae* | SI79 | $<1.0 \times 10^1$ | $3.9 \times 10^5$ | >99.9 |
| | | SI80 | $<1.0 \times 10^1$ | $3.9 \times 10^5$ | >99.9 |
| | | SI71 | $<1.0 \times 10^1$ | $3.9 \times 10^5$ | >99.9 |
| **Plastic Tiles** | | | | | |
| 476375-18 | *Staphylococcus aureus* | SI79 | $<1.0 \times 10^1$ | $5.4 \times 10^5$ | >99.9 |
| | | SI80 | $<1.0 \times 10^1$ | $5.4 \times 10^5$ | >99.9 |
| | | SI71 | $<1.0 \times 10^1$ | $5.4 \times 10^5$ | >99.9 |
| | *Klebsiella pneumoniae* | SI79 | $<1.0 \times 10^1$ | $4.7 \times 10^5$ | >99.9 |
| | | SI80 | $<1.0 \times 10^1$ | $4.7 \times 10^5$ | >99.9 |
| | | SI71 | $<1.0 \times 10^1$ | $4.7 \times 10^5$ | >99.9 |

[1]Lot No. SI79 refers to Lot No. CET-R 080408 SI79; Lot No. SI80 refers to Lot No. CET-R 080408 SI80; and Lot No. SI71 refers to CET-R 052208 SI71.

| MRID Number | Organism | Lot No. | Average No. Surviving | Microbes Initially Present | Percent Reduction |
|---|---|---|---|---|---|
| | | | (CFU/carrier) | | |
| 476375-31 | *Staphylococcus aureus* | SI79[1] | $<1 \times 10^1$ | $1.08 \times 10^8$ | >99.999 |
| | | SI82[1] | $<1 \times 10^1$ | $1.08 \times 10^8$ | >99.999 |
| | | SI71[1] | $<1 \times 10^1$ | $1.08 \times 10^8$ | >99.999 |
| | *Escherichia coli* | SI79[1] | $<1 \times 10^1$ | $1.1 \times 10^8$ | >99.999 |
| | | SI82[1] | $<1 \times 10^1$ | $1.1 \times 10^8$ | >99.999 |
| | | SI71[1] | $<1 \times 10^1$ | $1.1 \times 10^8$ | >99.999 |

[1]Lot No. SI79 refers to Lot No. CET-R080408 SI79; Lot No. SI82 refers to Lot No. CET-R080408 SI82; and Lot No. SI71 refers to CET-R052208 SI71.

## VI CONCLUSIONS

### A. Conclusions Regarding Use of the Product as a Disinfectant

1. The submitted efficacy data support the use of the product, PeridoxRTU, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 2-minute contact time:

| | |
|---|---|
| *Staphylococcus aureus* | MRID 476375-24 |
| *Salmonella enterica* | MRID 476375-24 |
| *Pseudomonas aeruginosa* | MRID 476375-24 |
| *Acinetobacter baumannii* | MRID 476375-29 |

| | |
|---|---|
| *Candida albicans* | MRID 476375-29 |
| *Campylobacter jejuni* | MRID 476375-29 |
| *Escherichia coli* O157:H7 | MRID 476375-29 |
| Extended spectrum β-lactamase *Escherichia coli* | MRID 476375-29 |
| Vancomycin-resistant *Enterococcus faecalis* | MRID 476375-29 |
| *Enterococcus hirae* | MRID 476375-29 |
| *Haemophilus influenzae* | MRID 476375-29 |
| *Klebsiella pneumoniae* | MRID 476375-29 |
| *Legionella pneumophila* | MRID 476375-29 |
| *Proteus vulgaris* | MRID 476375-29 |
| *Serratia marcescens* | MRID 476375-29 |
| *Shigella sonnei* | MRID 476375-29 |
| Methicillin-resistant *Staphylococcus aureus* | MRID 476375-29 |
| Community-acquired Methicillin-resistant *Staphylococcus aureus* (Genotype 300) | MRID 476375-29 |
| Penicillin-resistant *Streptococcus pneumoniae* | MRID 476375-29 |
| *Streptococcus pyogenes* | MRID 476375-29 |
| *Enterobacter aerogenes* | MRID 476375-30 |
| *Listeria monocytogenes* | MRID 476375-30 |
| *Salmonella typhimurium* | MRID 476375-30 |
| *Vibrio cholerae* | MRID 476375-30 |

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. In testing against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*, at least one of the product lots tested was at least 60 days old at the time of testing. Neutralizer effectiveness testing showed positive growth of the microorganisms. Viability controls were positive for growth. Sterility controls did not show growth. Bacteriostasis streaks exhibited no growth, when bacteriostasis controls were performed.

Note: The "Comments on the Submitted Efficacy Studies" section of this report identifies AOAC method deviations with regard to culture preparation, carrier drying, and subculture incubation. These deviations appear to be acceptable.

2. The submitted efficacy data support the use of the product, PeridoxRTU, as a disinfectant with fungicidal activity against *Aspergillus niger*, *Candida albicans*, and *Trichophyton mentagrophytes* on hard, non-porous surfaces in the presence of a 5% organic soil load for a 1-minute contact time. Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. [Note that repeat testing was conducted on one product lot against *Candida albicans* to evaluate for false positives.] Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

3. The submitted efficacy data support the use of the product, PeridoxRTU, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of at least a 5% organic soil load for a 2-minute contact time:

| | |
|---|---|
| Avian influenza virus (H5N1) | MRID 476375-11 |
| Adenovirus type 2 | MRID 476375-12 |
| Herpes simplex virus type 1 | MRID 476375-14 |

| | |
|---|---|
| Herpes simplex virus type 2 | MRID 476375-15 |
| Poliovirus type 1 | MRID 476375-16 |
| Avian influenza A virus (H3N2) | MRID 476375-17 |
| Human coronavirus | MRID 476375-19 |
| Influenza A virus | MRID 476375-20 |
| Influenza B virus | MRID 476375-21 |
| Feline calicivirus (a surrogate for Norovirus) | MRID 476375-22 and -23 |
| Reovirus | MRID 476375-25 |
| Respiratory syncytial virus | MRID 476375-26 |
| Rotavirus | MRID 476375-27 |

Recoverable virus titers of at least $10^4$ were achieved. In studies against Avian influenza virus (H5N1), Adenovirus type 2, Herpes simplex virus type 1, and Herpes simplex virus 2, cytotoxicity was observed in the $10^2$ and $10^3$ dilutions. Complete inactivation (no growth) was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level for these viruses. In studies against all other viruses (i.e., Avian influenza A virus (H3N2), Human coronavirus, Influenza A virus, Reovirus, Respiratory syncytial virus, Rotavirus), cytotoxicity was not observed, with the following two exceptions: (1) In studies against Poliovirus type 1, cytotoxicity was observed in the $10^{-1}$ dilution of one of five replicates for one of three product lots; and (2) in the initial study against Feline calicivirus, cytotoxicity was observed in the $10^{-1}$ dilution of four of five replicates for one of three product lots. Complete inactivation (no growth) was indicated in all dilutions tested for these viruses.

The studies against Feline calicivirus were performed at the same laboratory but under the direction of different study directors. Studies against Feline calicivirus tested at least two replicates per product lot.

4. The submitted efficacy data do not support the use of the product, PeridoxRTU, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of at least a 5% organic soil load for a 2-minute contact time:

| | |
|---|---|
| Human immunodeficiency virus type 1 | MRID 476375-10 |
| Rhinovirus | MRID 476375-13 |

At least a 3-log reduction in titer was not demonstrated beyond the cytotoxic level. Recoverable virus titers of at least $10^4$ were achieved. Cytotoxicity was observed in the $10^2$ dilutions (or the $10^2$ and $10^3$ dilutions). Complete inactivation (no growth) was indicated in all higher dilutions tested.

Note: For the study against Human immunodeficiency virus type 1, the laboratory reported a log reduction of $\geq$3.93; however, this value is based on the titer from the large volume inoculation. [See page 10 of the study assigned MRID 476375-10.] For the study against Rhinovirus, the laboratory reported a log reduction of $\geq$4.23; however, this value is based on the titer from the large volume inoculation. [See page 11 of the study assigned MRID 476375-13.]

**B. Conclusions Regarding Use of the Product as a Sporicidal Disinfectant Against *Clostridium difficile***

1. The submitted efficacy data (MRID 476375-28) support the use of the product, PeridoxRTU, as a sporicidal disinfectant against *Clostridium difficile* (spore form) (ATCC 700792) on hard, non-porous surfaces for a 7-minute contact time. Testing was conducted in the presence of an

organic soil load. At least a 99.9999 percent reduction of viable spores (within 10 minutes or less) was demonstrated. The control carrier counts were greater than 1 x $10^6$ CFU/carrier. Neutralization confirmation testing met the acceptance criterion of growth within ±1.0 $\log_{10}$ of the corresponding population control result. Purity controls were reported as pure. Sterility controls did not show growth. Acid resistance controls showed growth after 2 minutes of exposure.

**C. Conclusions Regarding Use of the Product as a Sanitizer and Sanitizing Rinse**

1. The submitted efficacy data (MRID 476375-18) support the use of the product, PeridoxRTU, as a sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* on hard, non-porous, non-food contact surfaces in the presence of a 5% organic soil load for a 30-second contact time. A bacterial reduction of at least 99.9 percent over the parallel control was observed within 30 seconds. At least one of the product lots tested was at least 60 days old at the time of testing. Neutralization effectiveness testing showed positive growth of the microorganisms. Sterility controls did not show growth.

2. The submitted efficacy data (MRID 476375-31) support the use of the product, PeridoxRTU, as a sanitizing rinse against *Staphylococcus aureus* and *Escherichia coli* on pre-cleaned, hard, non-porous, food contact surfaces for a 30-second contact time. A bacterial reduction of at least 99.999 percent over the parallel control was observed within 30 seconds. The numbers controls for the tested microorganisms met the laboratory acceptance criterion of 75-125 x $10^6$ CFU/mL. Neutralization confirmation testing met the acceptance criterion of growth within ±1.0 $\log_{10}$ of the numbers control. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

## VII RECOMMENDATIONS

**The registrant must correct the Ingredient Statement on the proposed label. The actives and other ingredients do not equal 100.0%. This revision must be consistent with the CSF.**

**A. Recommendations Regarding Disinfectant Claims**

1. The proposed label claims that the product, PeridoxRTU, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 2-minute contact time:

*Pseudomonas aeruginosa*
*Salmonella enterica*
*Staphylococcus aureus*

*Acinetobacter baumannii*
*Campylobacter jejuni*
*Enterobacter aerogenes*
*Enterococcus hirae*
Vancomycin-resistant *Enterococcus faecalis*
*Escherichia coli* O157:H7
Extended spectrum β-lactamase *Escherichia coli*

*Haemophilus influenzae*
*Klebsiella pneumoniae*
*Legionella pneumophila*
*Listeria monocytogenes*
*Proteus vulgaris*
*Salmonella typhimurium*
*Serratia marcescens*
*Shigella sonnei*
Methicillin-resistant *Staphylococcus aureus*
Community-acquired Methicillin-resistant *Staphylococcus aureus*
Penicillin-resistant *Streptococcus pneumoniae*
*Streptococcus pyogenes*
*Vibrio cholerae*

Adenovirus type 2
Avian influenza virus (H5N1)
Avian influenza A virus (H3N2)
Human coronavirus
Herpes simplex virus type 1
Herpes simplex virus type 2
Influenza A virus
Influenza B virus
Norovirus (using Feline calicivirus as a surrogate)
Poliovirus type 1
Reovirus
Respiratory syncytial virus
Rotavirus

In ten virucidal studies, ATS Labs sprayed the dried carriers for 25 pumps (approximately 15 to 20 seconds). The amount of product applied seems excessive. [See studies assigned MRID 476375-16, 476375-17, 476375-19 through 476375-23, and 476375-25 through 476375-27.]

These claims are acceptable as they are supported by the submitted data.

2. The proposed label claims that the product, PeridoxRTU, is an effective disinfectant against *Escherichia coli* on hard, non-porous surfaces in the presence of a 5% organic soil load for a 2-minute contact time [see pages 4 and 7 of the proposed label]. Data were not provided to support this claim. All references to use of the product as a disinfectant against *Escherichia coli* must be deleted from the proposed label. Note that data were provided to support claims against *Escherichia coli* O157:H7 and Extended spectrum β-lactamase *Escherichia coli*.

3. The proposed label claims that the product, PeridoxRTU, is an effective disinfectant against Human immunodeficiency virus type 1 and Rhinovirus on hard, non-porous surfaces in the presence of a 5% organic soil load for a 2-minute contact time [see pages 4, 5, and 8 of the proposed label]. As noted in the "Conclusions" section of this report, efficacy data did not demonstrate at least a 3-log reduction in titer beyond the cytotoxic level. All references to use of the product as a disinfectant against Human immunodeficiency virus type 1 and Rhinovirus must be deleted from the proposed label. Large volume virucide analyses require prior Agency approval and appropriate rationale.

4. The proposed label claims that the product, PeridoxRTU, is an effective fungicide against *Aspergillus niger*, *Candida albicans*, and *Trichophyton mentagrophytes* on hard, non-porous surfaces in the presence of a 5% organic soil load for a 1-minute contact time. These claims are acceptable as they are supported by the submitted data. *A. niger* (MRID No. 471064-01) was tested on any porous surfaces using 4% Peridox (diluted 24% Peridox , EPA Reg. No. 81073-1); therefore all porous fungicidal claims must be limited to *A. niger*. As stated in the DER dated July 23, 2007 for EPA Reg. No. 81073-1, carpet types must be specified for claims against *A. niger*.

5. The proposed label claims that the product, PeridoxRTU, is an effective tuberculocide on hard, non-porous surfaces in the presence of a 5% organic soil load for a 10-minute contact time [see pages 2, 3, 4, and 9 of the proposed label]. Data were referenced from 81073-1 to support this claim. All references to use of the product as a tuberculocide must be deleted from the proposed label.

**B. Recommendations Regarding Sporicidal Disinfectant Claims**

1. The proposed label claims that the product, PeridoxRTU, is an effective sporicidal disinfectant against *Clostridium difficile* on hard, non-porous surfaces in the presence of a 5% organic soil load for a 7-minute contact time. These claims are acceptable as they are supported by the submitted data. According to the Agency's interim guidance for sporicidal disinfectants against *Clostridium difficile* spores, all products for sporicidal disinfectants must carry a pre-cleaning step [http://www.epa.gov/oppad001/cdif-guidance.html]. For this reason, the directions for use of the product as a sporicidal disinfectant (on page 8 of the proposed label) must be revised to include a pre-cleaning step.

2. The Agency's interim guidance for sporicidal disinfectants against *Clostridium difficile* spores identifies special label instructions regarding cleaning prior to disinfection. The proposed label must be revised to include the following cleaning directions:

> "**Personal Protection**: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.
>
> **Cleaning Procedure**: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.
>
> **Infectious Materials Disposal**: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal."

**C. Recommendations Regarding Sanitizer/ Sanitizing Rinse Claims**

1. The proposed label claims that the product, PeridoxRTU, is an effective sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* on hard, non-porous surfaces for a 30-second contact time. These claims are now acceptable as they are supported by the submitted data. The complete study was provided to the Agency.

2. The proposed label claims that the product, PeridoxRTU, is an effective sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* on hard, non-porous surfaces for a 30-second contact time at half-strength [see pages 4 and 11 of the proposed label].

3. Efficacy data provided demonstrate that the product, PeridoxRTU, is an effective sanitizing rinse against *Staphylococcus aureus* and *Escherichia coli* on pre-cleaned, hard, non-porous, food contact surfaces for a 30-second contact time. The proposed label, however, does not include claims that the product is an effective sanitizing rinse on pre-cleaned, hard, non-porous, food contact surfaces for a 1-minute contact time. The applicant may wish to add such a claim to the proposed label.

**D. Miscellaneous Recommendations**

1. The proposed label claims that the product, PeridoxRTU, may be used to control mold on porous surfaces such as wood, tile grout, drywall, ceiling tile, carpets, upholstery cubical walls, wallpaper, posting boards, and wallboard [see pages 2, 5, 12, 16, 17, 18, 20, 21, 24, 25, and 26 of the proposed label]. These claims are not acceptable and must be deleted from the proposed label.

2. The following revisions are required on the proposed label:

- Under the "Ingredients Statement" of the proposed label, change the weight percentage of the other ingredients to read "95.37," so that the total amount adds up to 100%. The weight percentages currently add up to 100.03%.

- On page 4 of the proposed label, change "Human Coronavirus (SARS)" to read "Human Coronavirus." The Agency's acceptance of the data to support a label claim for Human coronavirus does not in any way support a label claim for the product as an effective disinfectant against the causative agent of Severe Acute Respiratory Syndrome (SARS).

- On pages 6 and 11 of the proposed label, change "porcelain" to read "glazed porcelain." Porcelain is a porous surface.

- On page 7 of the proposed label, add a statement similar to the following to the "Directions for Use" section: "For heavily soiled areas, a preliminary cleaning is required."

- Under the "Sanitization of Hard, Non-Porous, Inanimate Surfaces" section of the proposed label, replace all references to a "half-strength" use dilution with instructions to use the product at full strength.

- On page 13 of the proposed label, delete the porous surfaces identified in the paragraph beginning "Typically, non-porous surfaces ...." (e.g., wallboard, wood, masonry, cinderblock, carpet, textiles.) If the text is referring to sealed masonry, than revise the proposed label accordingly to state sealed masonry.

- On pages 16, 19, and 24 of the proposed label under Step 1, delete the porous surfaces identified (e.g., wallboard, wood surfaces, masonry, cinder block surfaces). If the text is referring to sealed masonry, than revise the proposed label accordingly to state sealed masonry.

- On pages 17 and 25 of the proposed label under the "Painted or Sealed Concrete, Masonry, or Cinder Block" section, delete the porous surfaces identified (e.g., wallboard, wood surfaces, masonry, cinder block surfaces). If the text is referring to sealed masonry, than revise the proposed label accordingly to state sealed masonry.

3. The following revisions are required the proposed label:

- Change the address for Clean Earth Technologies, Inc. to read "Earth City, MO."

- On page 3 of the proposed label, change "99.999%" to read "99.9999%."

- On page 4 of the proposed label, change "*Acinetobacter baumanii*" to read "*Acinetobacter baumannii*."

- On page 4 of the proposed label, change "*E. coli* 0157:H7" to read *E. coli* O157:H7."

- On page 4 of the proposed label, change "*Streptococcus pneumoniae* – Penicilin Resistant (PRSP)" to read "*Streptococcus pneumoniae* – Penicillin Resistant (PRSP)."

- Under the "Environmental Hazards" section of the proposed label on page 6, change "and permitting authority" to read "and the permitting authority."

- On pages 10 and 11 of the proposed label, change "Well wet all surfaces" to read "Thoroughly wet all surfaces."

- Under the "Sanitization of Hard, Non-Porous, Inanimate Surfaces" section of the proposed label on page 11, identify the bacteria against which the product is effective as a sanitizer.

- On page 13 of the proposed label, correct the spacing in the text identifying the five steps for comprehensive mold remediation. Some of the text is single spaced, and some of the text is double spaced.

- Re-number the pages of the proposed label, as there does not appear to be a page 28 of 28. Page 27 of 28 was the last page provided for the proposed label.

- Add ATCC numbers for each of the bacteria, fungi, and viruses identified.

- Remove the claim "mold killer" on the proposed label.

- Remove the descriptor "flesh-eating bacteria" following *Streptococcus pyogenes.*

- On page 13 of the proposed label, the contact time is 10 minutes. On page 15 of the proposed label, the contact time is 1 minute.